REMARKS

Claims 28, 30-32, 34, 39 and 41 remain pending in the present application. Claim 28 is amended to address formal matters discussed in the Examiner Interview of October 6, 2009. Claim 39 is amended to conform to the Examiner's indication of generic terminology for the term "Pluronics", derived from a known-in-the-art reference. No new matter is added.

During an interview conducted with the Examiner on October 6, 2009, Applicants' representative and the Examiner agreed that the "consisting of" transitional phrase in claim 28 should be adequate to overcome the prior art rejections, including Mori et al.

The Examiner requested Applicants' representative to (1) amend claim 28 such that the components of the composition were in the same portion of the claim. Such an amendment is submitted herewith, merely re-arranging the subject matter of claim 28 for clarity.

Rejection under 35 U.S.C. §112, second paragraph

Claim 39 is rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof in view of the accompanying amendment.

Applicants have amended claim 39 consistent with the Examiner's indication of the generic description of "Pluronics", as set forth at page 3 of the outstanding Office Action.

Rejection under 35 U.S.C. §102(b) over Mori et al.

Claims 28, 30-32 and 39 are rejected under 35 U.S.C. §102(b) as anticipated by Mori et al. (U.S. 6,239,177). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

Beginning at page 4 of the outstanding Office Action, the Examiner states:

> 10. Mori discloses composition in the form of patch or film (column 5, lines 13 and 58-65), the composition comprises tranilast (see the whole document with emphasis on the abstract; column 2, line 40; column 3, lines 39-51), solubilizer, absorption aid and dispersant for enhancing the absorption of tranilast into the skin (abstract; column 3, lines 55 to column 5, line 19), and water soluble polymers for adhesives, the polymers are selected from polyacrylic acid and acrylate copolymer, cellulose, gelatin, casein, polyvinyl alcohol, polyvinylpyrrolidone, polyethylene glycol, naturally occurring polysaccharide and can be used alone or in combination of two or more; fat soluble polymers can also be used as the adhesive (abstract; column 5, lines 20-47).
>
> 11. The tranilast meets the tranilast of claims 28, 31 and 32. Claims 31 and 32 are directed to the properties/characteristics of the composition.
>
> 12. The adhesive material such as the polyvinyl alcohol meets the requirements for biodegradable polymer of claim 28 and the polyvinyl alcohol of claim 30. When the adhesive material is a gum arabic or polysaccharide or gelatin, the biodegradable polymer of claim 39 is met.
>
> 13. The solubilizer, absorption aid and dispersant for enhancing the absorption of tranilast into the skin meet the limitation of the optional therapeutic agent of claim 28. (Emphasis added).

Applicants respectfully traverse the Examiner's contentions as to the disclosure of Mori et al. That is, Mori et al. invariably disclose compositions of Tranilast and water.

Mori et al. disclose external preparations containing Tranilast for high percutaneous absorption in the form of an aqueous base, containing a solubilizer

for Tranilast, a dispersant, an absorption aid, an adhesive and/or a shape retenting agent and water (abstract). Specifically, Mori et al. state:

> The present invention provides a preparation for external application and a method of producing it to achieve the above object, which preparation contains an aqueous base comprising tranilast, its salt, or a mixture thereof as an active ingredient, in which the aqueous base comprises a dissolution medium, a dispersant, an absorption aid, an adhesive, and/or a form-keeping agent, and water, the active ingredient is dissolved in the dissolution medium, and dispersed in the aqueous base by means of the dispersant. The present invention provides such a preparation for external application comprising tranilast and a patch for external application which comprises a support having the preparation for external application coated thereon. (Col. 3, lines 6-18; emphasis added).

The presently claimed composition is limited to having a delivery vehicle consisting of only Tranilast in a biodegradable polymer, in the form of a film, foam, fibers and filaments. The delivery vehicle has no solubilizer for Tranilast, no adhesive, and no water to form an aqueous base, as required by Mori et al. As such, anticipation cannot be said to exist.

> [R]ejections under 35 U.S.C. 102 are proper only when the claimed subject matter is identically disclosed or described in "the prior art"...[so as to] direct those skilled in the art to the compound without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference...There is nothing in the teachings relied upon by the Patent Office which "clearly and unequivocally" directs those skilled in the art to make this selection nor any indication that [patentee] ever made the selection himself. *In re Arkley, Eardley and Long*, 172 USPQ 524, 526 (CCPA 1972). (Emphasis added).

In order to address the presence of water in Mori et al., the Examiner suggests:

> The examiner disagrees with the applicant that Mori does not teach instant composition. The examiner agrees that the composition of Mori contains adhesive. But the adhesive of Mori is the biodegradable polymer of the instant claims. The examiner agrees that the composition

> of Mori contains contain solubilizer, dispersant, an absorption aid, but these agent meet the limitation of the optional therapeutic agent of claim 28 that enhances absorption of the tranilast into the skin for the therapeutic effect. With regards to the water, the examiner notes that the patch or film of Mori does not contain water. (Office Action, page 7; emphasis added).

Applicants respectfully submit that Mori et al. never disclose or even suggest that the patch proposed by Mori et al. "does not contain water". The Examiner's attention is directed to Mori et al.'s description of the manner of making patches:

> Further, the present invention relates to a method of producing a preparation for external application containing tranilast, which comprises dissolving an active ingredient selected from tranilast, its salt, or a mixture thereof in a dissolution medium, adding thereto a dispersant, and mixing the solution with an aqueous base comprising an absorption aid, an adhesive, and/or a form-keeping agent, and water, and to a method of producing a patch for external application which comprises coating the above preparation for external application on a support. (Col. 3, lines 19-28; emphasis added).

Mori et al. never suggest that their patch can be formed when the Tranilast composition does not contain water. At column 5, lines 17-19, Mori et al. state:

> The patch for external application is required not to cause contact irritation on the diseased part, to keep the form of the preparation, and to retain adhesiveness sufficiently, because the preparation is directly applied on the diseased part exposed on the skin surface. As the patch that satisfies the above requirements, aqueous types are preferably used though non-aqueous soft type plasters can also be used. (Emphasis added).

Applicants submit that the skilled artisan would recognize this portion of the Mori et al. disclosure to be directed to the nature of the "support" (see quotation from column 3, above) onto which the aqueous composition is coated. Nowhere do Mori et al. disclose making a patch in the absence of water, or even wherein water is driven off by drying. In each of Examples 1-4 (cols. 6-7), the

Tranilast composition is disclosed to contain water. In Test Example 2 (col. 8), Mori et al. disclose:

> In the same manner as in Examples 3 and 4, the preparations were prepared so as to make each of the amount of the absorption aid, propylene glycol and butanediol, 2%, 5%, and 10% and make the amount of N-methyl-2-pyrrolidone 2.5%. The resulting preparations were respectively spread on the support to give patches. Using the resulting patches, skin absorbability of the skin absorption aids, that is, propylene glycol, butanediol, and N-methyl-2-pyrrolidone, was evaluated by measuring the penetration rate of tranilast and the amount of tranilast accumulated in the skin. The results are shown in Table 2. The skin penetration rate was determined in accordance with the method as described in Test Example 1. The drug concentration in the skin was determined as described below. (Col. 8, lines 19-32; emphasis added).

It is important that the Examiner note Mori et al.'s failure to suggest drying of the composition on the coated patches. Clearly, water remains in the coatings.

Applicants further disagree that Mori et al.'s disclosure of solubilizers, absorption aids and dispersants for enhancing the absorption of tranilast into the skin meet the limitation of the optional therapeutic agent, as suggested by the Examiner in the quotation from page 5. Those of skill in the art recognize that such materials have no therapeutic value, and cannot therefore be considered to be "therapeutic agents" within the scope of the present claims.

Withdrawal of the rejection for lack of identity of subject matter is requested.

Rejection under 35 U.S.C. 103(a) over Mori et al.

Claims 28 and 30 are rejected under 35 U.S.C. 103(a) as obvious over Mori et al. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The deficiency of Mori et al. is discussed above and reiterated here. That is, Mori et al. fail to disclose or suggest delivery vehicles consisting of Tranilast or analogs thereof in a biodegradable polymer, but instead invariably disclose the addition of water in the form of an aqueous base to their formulations.

One of skill in the art would not have been motivated to eliminate water from the Mori et al. compositions, disclosed to have good transdermal properties (col. 2, lines 37-40), because to do so would render the Mori et al. compositions, unsatisfactory for its intended purpose.

> If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). **MPEP 2143.01**

Withdrawal of the rejection for failure to establish a *prima facie* case of obviousness is requested.

Rejection under 35 U.S.C. 103(a) over Mori et al. as evidenced by Isaji et al. and in view of Pope et al.

Claims 28 and 41 are rejected under 35 U.S.C. 103(a) as obvious over Mori et al. in view of Isaji et al. ("Tranilast: a New Application in the Cardiovascular Field as An Antiproliferative Drug", Cardiovascular Drug Reviews, Vol. 16, No. 3, pp. 288-299) in view of Pope et al. (US 5,498,822). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The deficiency of Mori et al. is discussed above and reiterated here. That is, Mori et al. fail to disclose or suggest delivery vehicles consisting of Tranilast or

analogs thereof in a biodegradable polymer, but instead invariably disclose the addition of water in the form of an aqueous base to their formulations.

Isaji et al. fail to disclose compositions containing a delivery vehicle consisting of Tranilast or its analogs in a biodegradable polymer. As such, Isaji et al. cannot cure the deficiency of Mori et al.

Pope et al. disclose topically administering a C18 to C26 aliphatic alcohol to a skin lesion in a pharmaceutically acceptable carrier (abstract) for treating or inhibiting the growth of hyperproliferative skin lesions, wherein the carrier may be white petrolatum, isopropyl myristate, lanolin or lanolin alcohols, mineral oil, sorbitan mono-oleate, propylene glycol, cetylstearyl alcohol, which can be combined with a detergent and mixed with water to form a lotion, gel, cream or semi-solid composition (col. 3, lines 41-49).

Pope et al. fail to cure the deficiency of Mori et al., since Pope et al. disclose mixtures of Tranilast in water.

One of skill in the art would not have been motivated to eliminate water from the Mori et al. compositions, disclosed to have good transdermal properties (col. 2, lines 37-40), because to do so would render the Mori et al. compositions, unsatisfactory for its intended purpose.

> If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). **MPEP 2143.01**

Withdrawal of the rejection for failure to establish a *prima facie* case of obviousness is requested.

Rejections for provisional nonstatutory double patenting

Claims 28, 30-32 and 39-41 are provisionally rejected for nonstatutory double patenting over claims 14, 19, 21-23, 27, 28, 31, 34, 37 and 39-41 of copending application no. 10/780,452, in view of Chandrasekar et al. ("Platelets and Restenosis") or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat"). Reconsideration of the double patenting rejection is requested in view of the accompanying amendment herein.

Claims 28, 30-32 and 39-41 are provisionally rejected for nonstatutory double patenting over claims 1-6, 11, 14-16, 19, 21-25, 27-34, 37, 40 and 41 of copending application no. 12/021,546, in view of Chandrasekar et al. ("Platelets and Restenosis") or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat"). Reconsideration of the double patenting rejection is requested in view of the accompanying amendment herein.

Applicants request that the requirement to respond to the double patenting rejections be held in abeyance until notification of allowable subject matter in the present application, at which time Applicants will consider submitting a Terminal Disclaimer over one or both of the cited copending applications.

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478 (15041).

If the Examiner has any questions or wishes to discuss this application, the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

Date: April 22, 2011

Michael J. Mlotkowski
Attorney for Applicants
Registration No. 33,020
(703) 584-3270

POST OFFICE ADDRESS to which Correspondence is to be sent:

Roberts, Mlotkowski, Safran & Cole
P.O. Box 10064
McLean, VA 22102